



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,959	03/22/2005	Sylvia Huber	NY-HUBR-1280 US	8761
24972 7590 06/22/2007 FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			EXAMINER BALASUBRAMANIAN, VENKATARAMAN	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 06/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,959

Applicant(s)

HUBER ET AL.

Examiner

/Venkataraman
Balasubramanian/

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/22/2005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending.

Information Disclosure Statement

References cited in the Information Disclosure Statement, filed on 3/22/2005, are made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the process of making 2-amino-4-chloro-6-alkoxy-pyrimidine from 2-amino-4,6-dichloro-pyrimidine using an alkali metal alkoxide in a polar aprotic solvent or solvent mixture, does not reasonably provide enablement for the process of making 2-amino-4-chloro-6-alkoxy-pyrimidine from 2-amino-4,6-dichloro-pyrimidine using an alkali metal hydroxides and an alcohol in a polar aprotic solvent or solvent mixture. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The following apply:

In evaluating the enablement question, following factors are considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or

Art Unit: 1624

absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1. The nature of the invention and the state of the prior art:

The invention is drawn to a process of making 2-amino-4-chloro-6-alkoxy-pyrimidine from 2-amino-4,6-dichloro-pyrimidine using an alkali metal alkoxide or a mixture of alkali metal hydroxides and an alcohol in a polar aprotic solvent or solvent mixture, Specification is not adequately enabled as to how to make 2-amino-4-chloro-6-alkoxy-pyrimidine from 2-amino-4,6-dichloro-pyrimidine using a mixture of alkali metal hydroxides and an alcohol in a polar aprotic solvent or solvent mixture, wherein the said mixture is protic in nature. Note both the alcohol and alkali metal hydroxide are protic in nature.

Reading the instant specification, it is clear that instant process is an improved process to reduce the amount of unreacted 2-amino-4,6-dichloro-pyrimidine (ADCP) in the final product 2-amino-4-chloro-6-alkoxy-pyrimidine. This appears to be the primary objective and from examples shown as inventive examples it is clear that use of polar aprotic solvent results in less than 0.2% of residual ADCP while the comparative examples which use an alcohol with a base result in more than 4% of residual ADCP. Use of such a system also reduces the over all yield of the product. See Trantolo et al., cited in the IDS. Specification offers no teachings or suggestion as to how to perform the said process using a mixture of alkali metal hydroxides and an alcohol in a polar aprotic solvent or solvent mixture yet obtain high yield and less than 0.2 % unreacted starting material.

Art Unit: 1624

2. The predictability or lack thereof in the art:

Hence the process as applied to the above-mentioned compounds claimed by the applicant is not an art-recognized process and hence there should be adequate enabling disclosure in the specification with working example(s).

4. The amount of direction or guidance present:

Examples illustrated in the experimental section or written description offer no guidance or teachings as to how perform the process of making 2-amino-4-chloro-6-alkoxy-pyrimidine from 2-amino-4,6-dichloro-pyrimidine using a mixture of alkali metal hydroxides and an alcohol in a polar aprotic solvent or solvent mixture, when protons are present in the reaction medium arising from the reagents and or reactants used. A process for such a combination is not shown and hence the instant process would be an obvious variant of known process stated above.

5. The presence or absence of working examples:

Although examples 1-3 show the process, they are limited to proton free solvent system with no reactivity. There are no representative examples showing the viability of the process for plurality of reactive alkali metal hydroxides and alcohol mixture embraced in the instant claims.

6. The breadth of the claims:

Specification has no support, as noted above, for all compounds generically embraced in the claim language would lead to desired alkoxy pyrimidine compound with said alkali metal hydroxides and alcohol mixture and there is also no valid chemical reasoning for

Art Unit: 1624

one trained in the art to expect same in view of prior art teachings and showing of comparative examples in the specification.

7. The quantity of experimentation needed:

The quantity of experimentation needed would be an undue burden on skilled art in the chemical art since there is inadequate guidance given to the skilled artisan for the many reasons stated above. Even with the undue burden of experimentation, there is no guarantee that one would get the product of desired purity, namely 2-amino-4-chloro-6-alkoxy-pyrimidine embraced in the instant claims in view of the prior art teachings.

Thus, factors such as "sufficient working examples", the "level of skill in the art and predictability, etc., have been demonstrated to be sufficiently lacking in the case for the instant claims.

It is noted that the comparative examples provided in the specification are meant to show unexpected results over the prior art process. Lack of any such showing for the process using alkali metal hydroxides and alcohol would render the process obvious variant of known process cited above. Also it is noted that Moon et al., provided by the applicants uses alkoxide and alcohol. A comparative data with this combination is not provided in the specification to show unexpected result. Note Ex parte Gelles 22 USPQ 2nd 1318, especially the following quote: " The evidence relied upon also should be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter " as a class" relative to prior art subject matter."

Art Unit: 1624

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).


Venkataraman Balasubramanian

6/19/2007